

Appl. No. 09/609,622
Atty. Docket No. P-122
Reply to Office Action dated January 31, 2003
Customer No. 27752

REMARKS

Upon entry of the amendments and cancellations herein, Claims 15 – 24 will be pending in the present application. No additional claims fee is believed to be due.

Claims 10 – 13, previously withdrawn, are canceled without prejudice.

Claim 15 has been amended to clarify that, while the composition comprises at least one of sorghum and barley, the composition may optionally comprise one or more further carbohydrates as well. Claim 15 has also been amended to more properly conform with Markush group practice.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

The Rejection Under 35 USC § 103(a)

Claims 15 – 24 have been rejected under 35 USC 103(a) as being unpatentable over the combination of U.S. Patent No. 5,626,849 (the '849 patent'), the Purina CNM Veterinary Product Guide ('Purina'), and U.S. Patent No. 5,240,962 (the '962 patent'). Applicants respectfully traverse this rejection for two reasons. First, there would have been no motivation to combine the present references in order to arrive at the present invention. Even further, a combination of the present references even fails to suggest the invention. Moreover, even if a motivation or a suggestion of the invention was established, the obviousness argument is overcome by Applicant's showing of unexpected results. As such, Applicant asserts that the claimed invention is indeed non-obvious and that the rejection should be withdrawn.

One of ordinary skill in the art would not have been motivated to combine the cited references, and Applicant asserts that the Examiner is using impermissible hindsight to do so. Indeed, the '849 patent merely suggests the use of chromium and L-carnitine, at very specific levels, for use in the described dietary supplements. As this fails to teach or even suggest the elements of Applicant's claims, including the recitation of Vitamin A and a carbohydrate selected from sorghum, barley, and mixtures thereof, one of ordinary skill must have been motivated to combine another reference in order for the Examiner to properly construct the argument of obviousness. However, folding in Purina and the '962 patent would not have been motivated for several reasons. First, the Examiner appears to have overlooked the totality of Purina. The Examiner states that the weight management diet disclosed by Purina uses corn. However, the Examiner

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does not recognize in the Office Action that not only the weight management diet but rather *each and every diet described by Purina uses corn* (in the form of ground yellow corn or corn gluten meal, depending on the diet). This includes diets suggested by Purina for the following conditions - - ascites, colitis, congestive heart failure, constipation, critical care, diabetes mellitus, diarrhea (small bowel), diarrhea (large bowel), edema, enteritis, exocrine pancreatic insufficiency, fluid retention, gastritis, geriatrics, hepatic disease, hepatic encephalopathy, hyperlipidemia, hypertension, inflammatory bowel disease, lymphangectasia, malabsorption / maldigestion, obesity, pancreatitis, and renal failure.

As such, it is not an appropriate characterization to argue that Purina is selecting corn for specific use in weight management diets. Indeed, a thorough review of Purina indicates that the described weight management diets are formulated to achieve low fat, high fiber, and reduced caloric content attributes.

Even further, it is not even appropriate to argue that one of ordinary skill in the art would have equated sorghum or barley with corn for weight management purposes in view of the disclosure of the '962 patent. Read in context, the '962 patent states that the phenols described for use in weight management may be combined in animal feeds. The '962 patent merely states that animal feeds often contain grains such as corn, sorghum, wheat, barley, oats, and the like. The described grains are described merely as vehicles for the feed, not active ingredients for weight management purposes (the described phenols provide this benefit, as described by the '962 patent). There is absolutely no teaching or suggestion that, when utilized as a weight management active, sorghum or barley, or even corn, should be used. Indeed, the '962 patent describes wheat and oats, which are not low glycemic grains. And again, stating that sorghum or barley as described by the '962 patent can be interchanged with the corn of Purina specifically for weight management purposes is a tenuous and inappropriate connection, since Purina describes the use of corn for all described diets.

Moreover, even assuming *arguendo* that the combination of references would have been appropriate, the cited combination of references does not teach or suggest all of Applicant's claim limitations. Specifically, Applicant's independent Claim 15 requires effective weight reducing amounts of each of the following: L-carnitine, chromium, Vitamin A, and at least one carbohydrate selected from sorghum, barley, and mixtures thereof, wherein these components are formulated as a solid pet food. The cited combination of references fails to teach effective weight reducing amounts of Vitamin A, since there are no descriptions of Vitamin A for purposes of effecting weight management (Purina may utilize Vitamin A in its weight management diet, but

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just like its use of corn, the Vitamin A is used for *all* described diets). Moreover, the '849 and '962 patents fail to describe or even suggest the use of Vitamin A for effecting weight management.

Even further, the '849 patent fails to describe weight management effective amounts of sorghum, barley, or both. Indeed, the '849 patent describes the use of hydrolyzed oat flour, only for decreasing LDL cholesterol. And again, as already set forth, Purina and the '962 patent fail to teach or even suggest sorghum or barley for use as effective weight management grains; further, Purina describes corn for *all* diets not just the weight management diet.

Moreover, with respect to dependent Claims 19 – 24, the cited combination of reference further fails to teach or suggest these further refined elements. For example, Claim 19 recites compositions comprising from about 15 to 195 ppm L-carnitine, from about 10 to about 500 micrograms of chromium, and from about 50,000 IU to about 1,000,000 IU of Vitamin A *per kilogram*. These are exceedingly lower doses of L-carnitine and chromium relative to those described in the '849 patent -- the '849 patent describes 50 to 125 mg of L-carnitine and 25 to 100 micrograms of chromium *per 7.325 grams of the described dietary supplement*.

As such, the cited combination of references fails to obviate the present invention because: 1) there would have been no motivation to combine, for the above reasons; and 2) the cited combination fails to teach or suggest each and every element of the claimed invention.

Even assuming *arguendo* that a *prima facie* case had been established, Applicants have overcome the presumption of obviousness by a showing of unexpected results. Page 9 of the specification reports the results of a comparative feeding study. At page 9, it is reported that "Diet B," which comprises a low glycemic index carbohydrate source (sorghum and barley), produced more preferable weight loss relative to "Diet A." While the Examiner objects to this data based on an alleged lack of detail of the ingredients of each of the diets, Applicant refers the Examiner to page 7 of the specification which states that Diet A was Hill's® Prescription Diet® w/d® Canine and that Diet B was Eukanuba Veterinary Diets® Nutritional Weight Maintenance Formula™ Glucose-Control™/Canine supplemented with the described amounts of chromium and sorghum and barley. A current description of Hill's® Prescription Diet® w/d® Canine and Eukanuba Veterinary Diets® Optimum Weight Control/Canine, obtained from the internet as of the date of signature of this paper, is appended hereto for the Examiner's convenience. Moreover, the examples set forth in the specification do not restrict the invention to the specific chromium source described therein, and do not limit the showing.

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Accordingly, Applicant asserts that the invention as claimed herein would not have been obvious in view of the cited combination of references. To sum, the use of sorghum and / or barley achieves unexpected effects when combined with the remaining components of the claimed compositions. The use of sorghum or barley for this purpose is neither taught nor suggested in the cited combination of references. As stated, the Examiner has appears to have constructed the rejection by substituting corn with sorghum or barley based on the following tenuous and improper connections: 1) the '962 patent states that animal feeds can contain corn, sorghum, wheat, barley, oats and the like (but the Examiner fails to recognize that the use of such grains is as a vehicle only, not as a weight management active); and 2) Purina uses corn in its weight management diet (but the Examiner fails to recognize that corn is used in *all* of the described diets, not just the weight management diet). Moreover, Applicant has provided evidence of unexpected results as set forth in the specification as filed. In view of the foregoing, and these unexpected results, Applicant respectfully requests the prompt withdrawal of the present rejection based on obviousness.

CONCLUSION

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a). Early and favorable action in the case is respectfully requested.

Applicants have made an earnest effort to place the present application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 15 – 24 as presented herein.

Respectfully submitted,
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